

**Commonwealth of Massachusetts  
Department of Mental Health  
Central Office Research Review Committee**

**Serious Adverse Event Report Form**

**1. PRIMARY INVESTIGATOR INFORMATION:**

**Protocol Number:** \_\_\_\_\_  
**Protocol Title:** \_\_\_\_\_  
**Principal Investigator:** \_\_\_\_\_  
**Telephone Number:** \_\_\_\_\_ **Fax Number:** \_\_\_\_\_  
**Email Address:** \_\_\_\_\_  
**Mailing Address:** \_\_\_\_\_  
\_\_\_\_\_

**2. SUBJECT INFORMATION:**

**Birth Date:** \_\_\_\_\_ **Gender:** ☐ M ☐ F  
**DMH Client:** ☐ Y ☐ N  
**Current Status of the Client:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**3. EVENT INFORMATION**

**Date Event Started:** \_\_\_\_\_ **Date Event Ended:** \_\_\_\_\_  
**Site of Event:** \_\_\_\_\_  
**Event Summary Description.** Give a brief description of the circumstances leading to the adverse event, describe its course (include diagnosis/syndrome, component signs and symptoms); and indicate any unscheduled diagnostic procedures or treatment measures and corresponding dates. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Death** ☐ Yes ☐ No      **Hospitalization** ☐ Yes ☐ No      **Life Threatening** ☐ Yes ☐ No  
**Disability** ☐ Yes ☐ No

4. **RELATIONSHIP OF SERIOUS ADVERSE EVENT TO RESEARCH**

☐ Unrelated (Clearly not related to the research)

☐ Unlikely (Doubtfully related to the research)

☐ Possible (May be related to the research)

☐ Probable (likely related to the research)

☐ Definite (Clearly related to the research)

**Have similar adverse events occurred on this protocol?** ☐ Yes ☐ No

**If "Yes," how many?** \_\_\_\_\_ **Please describe:** \_\_\_\_\_

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5. **CORRECTIVE ACTION:**

**What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the Research Review Committee for review and approval of any of the steps checked below:**

☐ no action required

☐ amend the consent procedures

☐ amend the protocol

☐ suspend the protocol

☐ terminate the protocol

☐ inform current subjects

☐ other (describe below)

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**Investigator Signature** \_\_\_\_\_ **Date** \_\_\_\_\_